

### REMARKS

This is a full and timely response to the final Official Action mailed August 17, 2010 (the “Office Action” or “Action”). Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

#### Request for Continued Examination (RCE):

Applicant hereby requests Continued Examination for this application and entry and consideration of this amendment consequent thereto.

#### Claim Status:

Under the imposition of a previous Restriction Requirement, claims 19-44 and 47-49 were withdrawn from consideration and are so marked herein. Withdrawn claim 25 was previously cancelled without prejudice or disclaimer. The withdrawn claims have been amended herein consistent with the pending claims. Specifically, withdrawn claims 19, 24, 26, 29, 33, 37, 39, 40, 42, 47 and 49 have been amended. Consequently, upon the allowance of claim 1, claims 19-24, 26-44, and 47-49 will be entitled to rejoinder and allowance. MPEP §821.04.

By the foregoing amendment, pending claims 1, 3, 10, 15 and 45 have also been amended. Pending claims 3, 10 and 15 as well as withdrawn claims 19, 24, 26, 29, 33, 37, 39, 40, 42, 47 and 49 have been amended to correct informalities. Pending claim 15 has been amended to reinstate “drying agent” into the list of addition agents that can be added to the jettable solution. Further, original claims 6-8 and 16 were previously cancelled without prejudice or disclaimer. Thus, claims 1-5, 9-15, 17, 18, 45 and 46 are currently pending for further action.

35 U.S.C. §112, first paragraph:

In the recent Office Action, claims 1-5, 9-15, 17-18, and 45-46 were rejected under 35 U.S.C. §112, first paragraph. These claims have been carefully reviewed in light of the Examiner's comments.

While Applicant does not necessarily agree that these claims fail to comply with the written description requirement, independent claims 1 and 45 have been amended herein to address the issues raised by the Examiner under 35 U.S.C. §112, first paragraph. Following this amendment, all the remaining claims are believed to be in compliance with 35 U.S.C. §112 and notice to that effect is respectfully requested.

Prior Art:Rejection under 35 U.S.C. §103(a):

(1). In the recent Office Action, claims 1-3, 5, 10, 15, 17, and 45-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,790,435 to Ma et al. ("Ma") as evidenced by The Merck Manuals, Diagnosis and Treatment of Skin Disorder ("The Merck Manuals"). Furthermore, claims 11-12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ma as evidenced by the Merck Manuals in view of Woo (Formulation and physicochemical properties of macro- and micro-emulsions prepared by interfacial ion-pair formation between, see IDS) ("Woo"). For at least the following reasons, these rejections should be reconsidered and withdrawn.

Claims 1 and 45:

Claim 1 recites:

A jettable solution **on an edible structure;**

**said edible structure including one of a polymeric organic film former or a paper organic film former;**

**said jettable solution including:**

an oil;

an edible surfactant;

an aqueous solution;

and

a pharmaceutically active ingredient solubilized into said oil;

in which said oil, said pharmaceutically active ingredient, said surfactant, and said aqueous solution form a microemulsion;

in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter.

(Emphasis added).

Similarly, claim 45 recites:

A jettable solution **on an edible structure;**

**said edible structure including one of a polymeric organic film former or a paper organic film former;**

**said jettable solution including:**

a water insoluble pharmaceutically active ingredient;

and

a means for forming an emulsion including said pharmaceutically active ingredient,

in which said means for forming an emulsion is configured to create said jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter.

(Emphasis added).

Support for the amendments to claims 1 and 45 can be found in Applicant's originally filed specification at, for example, paragraphs [0024] and [0047] and in original claim 36.

In contrast, Ma does not teach or suggest a jettable solution on an edible structure. (Claims 1 and 45). Rather Ma describes an antiperspirant composition which can be applied to the skin. (Ma, column 3, lines 16-20). Furthermore, neither does combining Woo with Ma teach or suggest a jettable solution on an edible structure. Woo describes water-in-oil and oil-in-water emulsions prepared using stearic acid and L-arginine or L-lysine (Woo, pg. 105-109).

Therefore, neither the Ma reference alone nor the combination of Woo with Ma can be applied as prior art against the present application under 35 U.S.C. §103(a). The rejection of claims 1-3, 5, 10, 15, 17, and 45-46 based on Ma should be withdrawn. Furthermore, the rejection of claims 11-12 based on the combination of Woo with Ma should be withdrawn.

(2). In the recent Office Action, claims 1-5, 9-10, 13-15, 17, and 45-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication US 2002/0143072 to Aust ("Aust"). Furthermore, claims 11-12 and 18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Aust as evidenced by the Merck Manuals in view

of Woo. For at least the following reasons, these rejections should be reconsidered and withdrawn.

Claims 1 and 45:

Claim 1 recites:

A jettable solution **on an edible structure;**  
**said edible structure including one of a polymeric organic film former or a paper organic film former;**  
**said jettable solution including:**  
    an oil;  
    an edible surfactant;  
    an aqueous solution;  
    and  
    a pharmaceutically active ingredient solubilized into said oil;  
in which said oil, said pharmaceutically active ingredient, said surfactant, and said aqueous solution form a microemulsion;  
in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter.  
(Emphasis added).

Similarly, claim 45 recites:

A jettable solution **on an edible structure;**  
**said edible structure including one of a polymeric organic film former or a paper organic film former;**  
**said jettable solution including:**  
a water insoluble pharmaceutically active ingredient;  
and  
a means for forming an emulsion including said pharmaceutically active ingredient,  
in which said means for forming an emulsion is configured to create said jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter.  
(Emphasis added).

In contrast, Aust does not teach or suggest a jettable solution on an edible structure. (Claims 1 and 45). Rather Aust describes a microemulsion composition “for topical, oral, nasal, anal, ophthalmic, or vaginal applications”. (Aust, paragraph [0012]). Furthermore, neither does combining Woo with Aust teach or suggest a jettable solution on an edible structure. Woo describes water-in-oil and oil-in-water emulsions prepared using stearic acid and L-arginine or L-lysine (Woo, pg. 105-109).

Therefore, the Aust reference cannot be applied as prior art against the present application under 35 U.S.C. §103(a). And, the rejection of claims 1-5, 9-10, 13-15, 17, and

45-46 based on Aust should be withdrawn. Furthermore, the rejection of claims 11-12 and 18 based on the combination of Woo with Aust should be withdrawn.

Double Patenting:

Non-statutory obviousness-type double patenting rejection:

In the recent Office Action, claims 1-3, 10, 13, 15, and 45-46 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-14, 16 and 21 of U.S. Patent No. 7,166,154 to Barreto (“Barreto”). For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claims 1 and 45:

Claim 1 recites:

A jettable solution **on an edible structure;**

**said edible structure including one of a polymeric organic film former or a paper organic film former;**

**said jettable solution including:**

an oil;

an edible surfactant;

an aqueous solution;

and

a pharmaceutically active ingredient solubilized into said oil;

in which said oil, said pharmaceutically active ingredient, said surfactant, and said aqueous solution form a microemulsion;

in which said jettable solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter. (Emphasis added).

Similarly, claim 45 recites:

A jettable solution **on an edible structure;**  
**said edible structure including one of a polymeric organic film former or a paper organic film former;**

**said jettable solution including:**

a water insoluble pharmaceutically active ingredient;  
and  
a means for forming an emulsion including said pharmaceutically active ingredient,

in which said means for forming an emulsion is configured to create said jettable solution with a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 to 60 dynes per centimeter. (Emphasis added).

In contrast, claims 13-14, 16 and 21 of Barreto do not teach or suggest a jettable solution on an edible structure. (Claims 1 and 45).

Therefore, Applicant respectfully asserts that filing a terminal disclaimer to remove the non-statutory obviousness-type double patenting rejection based on claims 13-14, 16 and 21 of Barreto is unnecessary. The double patenting rejection should be withdrawn.



Conclusion:

In view of the preceding arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments in future papers supporting the patentability of any of the claims, including the separate patentability of the dependent claims not explicitly addressed herein. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

The absence of a reply to a specific rejection, issue, or comment in the Office Action does not signify agreement with or concession of that rejection, issue or comment. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicant expressly does not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

If the Examiner has any comments or suggestions which could place this application in better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: October 27, 2010

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